K081476

Summary of Safety and Effectiveness

AUG - 8 2008

Submitter: Christopher Scott
Surgical Concept Designs
307 Prospect Ave – 2G
Hackensack, NJ 07601

Date Prepared: May 15, 2008

Device: Surgical Concept Designs Surgical Drape

Classification: 79 KKX - Surgical drape and drape accessories, 21 CFR 878.4370 Class II

Predicate Device: Advance Medical Designs Slush Drapes – K053594
Microtek Medical, Inc. Equipment Drapes – K050322

Device Description: The Surgical Concept Designs Surgical Drape is a generally tubular sleeve of polyethylene film with an integrated equipment attachment feature at one end made from polycarbonate, with stainless steel pegs and a butyl rubber gasket.

Intended Use: The Surgical Concept Designs Surgical Drape is an equipment cover used to cover medical equipment in a surgical setting. It is to be used in general surgery.

Comparison to Predicates:
The Surgical Concept Designs Surgical Drape consists of a polyethylene drape cut and configured to a specification with an integrated equipment attachment feature. The device is equivalent to the Microtek Medical Equipment Drape and Advance Medical Designs Slush Drapes which are also surgical drapes manufactured from polymer film cut and configured to a specification.

Surgical Concept Designs has determined that any differences in the proposed device will not impact the safety or effectiveness of the surgical drape for its intended use. Testing has shown that the proposed device meets the applicable requirements of the standards for surgical drapes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 8 2008

Mr. Christopher Scott
President
Surgical Concept Designs
307 Prospect Avenue, Suite 2G
Hackensack, New Jersey 07601

Re: K081476
Trade/Device Name: Surgical Concept Designs Surgical Drape
Regulation Number: 878.4370
Regulation Name: Surgical drape and drape Accessories
Regulatory Class: II
Product Code: KKX
Dated: July 30, 2008
Received: August 4, 2008

Dear Mr. Scott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

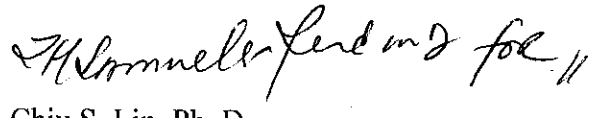
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K081476

Device Name: Surgical Concept Designs Surgical Drape

Indications for Use:

The Surgical Concept Designs Surgical Drape, Model #01001 is used to cover medical equipment in a surgical setting. It is to be used in general surgery.

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheila N Murphy MD

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K081476